28. (Twice Amended) An apparatus for treating a disease process in the vicinity of a luminal structure, comprising:

a balloon catheter having a shaft and an inflatable balloon; and

a tube segment adapted to be carried by and cover said balloon, said tube segment including radioactive material having varying concentrations of radioactive material for producing radiation for treating a disease process, said tube segment producing a radiation dose which varies along at least one dimension of the tube segment.

Please cancel claims 5, 14-21, 31 and 32, without prejudice or disclaimer to present these claims in this or another application.

Remarks

Reconsideration and allowance of the present application in view of the foregoing amendments and accompanying remarks are respectfully requested.

Claims 1-32 are pending in this application, and claims 1, 8, 22, 25, 29 and 30 are being amended. Claims 5, 14-21, 31 and 32 are being cancelled. Claims 1-4, 6-13, and 22-30 are pending, and of those claims 1, 8, 22, 25 and 28 are independent.

In the Office Action dated June 11, 2002, the Examiner stated that Figure 1 should be designated by a legend such as -Prior Art- because only that which is old is illustrated. See MPEP § 608.02(g). The Examiner stated that a proposed drawing

correction or corrected drawings are required in reply to the Office Action to avoid abandonment of the application, and that the objection to the drawings will not be held in abeyance. In response, applicant submits herewith a proposed drawing correction in accordance with the Examiner's requirement.

The Examiner stated that the disclosure is objected to because of the following alleged informalities:

a. In the sentence on page 1, lines 6-8, the current status of the parent application should be provided.
b. On page 8, line 25, "adhesing" apparently should read --adhering--.

In response, applicant has amended the specification to address the Examiner's objections.

The Examiner stated that claim 5 is objected to because of the following alleged informalities: in line 3, "adhesing" apparently should read -adhering--. Applicant has cancelled claim 5.
The Examiner stated that claim 8 is objected to because of the following alleged informalities: in line 7, "collapsible" apparently should read -collapsible--. In response, applicant has amended claim 8 to address this objection.

The Examiner stated that claim 25 is objected to because of the following alleged informalities: in line 6, --segment—apparently should be inserted following "tube" in order to maintain consistent terminology for the limitation in the claim. In response, applicant has amended claim 25 to address this objection.

The Examiner stated that claim 28 is objected to because of the following alleged informalities: in line 9, --segment--apparently should be inserted following "tube" in order to maintain consistent terminology for the limitation in the claim. In response, applicant has amended claim 28 to address this objection.

The Examiner rejected claims 1-24 and 29-32 under 35 U.S.C. 112, second paragraph, as being allegedly indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner stated that, regarding claims 1, 5, 8 and 14, the pronoun "its" renders the claims indefinite. In response, applicant has amended claims 1 and 8 to address the Examiner's rejection. Claims 5 and 14 have been cancelled.

The Examiner stated that claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being allegedly incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The Examiner stated that the omitted step is an additional method step in order to disclose that a radiation dose is actively being administered to the patient. The Examiner stated that the claim discloses that the balloon catheter has a tube segment including a radioactive material, but there is no indication that a radiation dose is being administered to the patient until the balloon catheter is removed "after a desired radiation dose has been achieved." In response, applicant is amending this claim as suggested by the Examiner.

The Examiner stated that, regarding claims 29 and 30, the preamble of the claims is inconsistent with that of the

corresponding independent claim 28. The Examiner stated that claim 28 recites an apparatus and claims 29 and 30 recite a tube segment. The Examiner stated that it is unclear whether claims 29 and 30 are further limiting the combination of elements that form the apparatus or merely the tube segment of the apparatus. In response, applicant is amending claims 29 and 30 to address this rejection.

The Examiner stated that claim 31 recites the limitation "the distal end of a tube" in line 5 and that there is insufficient antecedent basis for this limitation in the claim. The Examiner stated that the tube is not disclosed as having a distal end prior to this recitation. Applicant has cancelled claim 31.

The Examiner rejected claims 1, 3-8, 10-14, 16, 17 20 and 22-24 as being allegedly anticipated by Fischell et al. ('282). The Examiner stated that Fischell et al. teach a balloon catheter 40 for irradiation of arterial stenosis including an inflatable balloon 51 and a cylindrical, elastic radioactive source 52 both located coaxially at a distal end of the balloon catheter. The Examiner stated that the cylindrical radioactive source is a tube segment 52 formed of a mixture of radioactive material and non-radioactive material. The Examiner stated that the tube segment 52 can be an expandable and collapsible material, and is adhered to either the outer surface or the inner surface of the balloon 51. The Examiner stated that the radioactive material is present in a predetermined dosage per surface area when the tube is in an unexpanded state, but that dosage changes as the tube 52 is expanded. The Examiner stated that a plurality of tube segments are provided having different sizes and doses so that a given tube segment can be selected according to a desired radiation dosage. The Examiner stated that in an alternative embodiment, the tube segment 73 is mounted to a shaft 12 of the catheter 60

inside of the balloon 72. In operation, the balloon of the balloon catheter including the tube segment formed of a radioactive material is inserted into a luminal structure, is inflated with a gaseous media such as carbon dioxide, is deflated after a desired radiation dose has been achieved, and is finally removed from the luminal structure.

The Examiner stated that claims 25-27 are rejected as being allegedly anticipated by Columbo et al. The Examiner stated that Columbo et al. teach a cylindrical stent for treating a disease process in a luminal structure. The Examiner stated that the stent is a tubular segment and includes a radioactive material for producing radiation. The Examiner stated that the radiation dose varies along axial and longitudinal dimensions of the tube segment.

The Examiner stated that claims 31 and 32 are rejected as being allegedly anticipated by Hehrlein. The Examiner stated that Hehrlein teaches a balloon catheter 1 for eliminating vessel restrictions or stenoses; for inhibiting restenosis in arteries, veins or vessel implants; or for inhibiting the growth of tumors. The Examiner stated that balloon catheter 1 includes a shaft and an inflatable balloon 2 having at least one radioactive nuclide species in or on the wall of the balloon 2. The Examiner stated that a tube segment 4 is provided that is adapted to cover the balloon and to be moved longitudinally relative to the balloon to uncover the balloon to thereby respectively shield and unshield the radioactive material from the luminal structure when deployed. The Examiner stated that the tube segment 4 includes radioactive shielding material (col. 3, lines 3-5). The Examiner stated that the subject matter of claims 31 and 32 was not disclosed in parent applicant Serial No. 09/271,063, and that,

therefore, claims 31 and 32 are not awarded the benefit of the earlier filing date.

The Examiner stated that claims 2, 9, 15 and 21 are rejected as being allegedly obvious over Fischell et al. ('282) in view of Hess ('168). The Examiner stated that Fischell et al. teach all of the limitations of the claims except that the radioactive material is in the form of a coating. The Examiner stated that it is well known in the art that a non-radioactive material can [be] provided with radioactive characteristics by coating the non-radioactive material with a radioactive material. The Examiner stated that Hess teaches a stent 74 which is coated with a radioactive material in order to assist in preventing restenosis of an artery. The Examiner stated that it would have been an obvious engineering design choice to one skilled in the art at the time the invention was made to make a radioactive tubular segment similar that of Fischell et al. by coating a tubular segment with a radioactive material in view of the teachings of Hess.

The Examiner stated that claims 18 and 19 are rejected as being allegedly obvious over Fischell et al. ('282) in view of Waksman et al. The Examiner stated that Fischell et al. teach all of the limitations of the claims except that the tubular segment is sheathed in foil and can comprise a coil. The Examiner stated that Waksman et al. teach an apparatus for treating a desired area in the vascular system of a patient. The Examiner stated that the apparatus includes a balloon catheter 254 having a shaft 272 and an inflatable balloon 274, and a tube segment 22 including radioactive material mounted on the shaft 272 inside of the balloon 274. The Examiner stated that the tube segment 22 can be sheathed in foil and configured as a coil 9 (Figure 11).

The Examiner stated that it would have been an obvious engineering design choice to one skilled in the art a the time the invention was made to provide a radioactive tubular segment similar that of Fischell et al. with a foil sheath and a coil in view of the teachings of Waksman et al. in order to contain radioactive microparticles within the tubular segment.

The Examiner stated that claims 28-30 are rejected as being allegedly obvious over Columbo et al. in view of Hess ('466). The Examiner stated that Columbo et al. teach a cylindrical stent for treating a disease process in a luminal structure. The Examiner stated that the stent is a tubular segment and includes a radioactive material for producing radiation. The Examiner stated that the radiation dose varies along axial and longitudinal dimensions of the tube segment.

The Examiner stated that stent is a balloon expandable stent (claim 15). The Examiner stated that Columbo et al. teach all of the limitations of the claims except that the apparatus further includes a balloon catheter. The Examiner stated that Hess ('466) teaches an apparatus for restenosis treatment including a balloon catheter including a shaft 72 and an inflatable balloon 78 and a stent 74. The Examiner stated that it would have been obvious to one having ordinary skill in the art the time Applicant's invention was made to use a balloon catheter with a tubular stent similar to that of Columbo et al. in view of the teachings of Hess in order to deliver the stent to an area within an artery or vein for treatment.

The Examiner stated that claims 1-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No.

6,200,256 B1. The Examiner stated that, although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are merely broader than those of the patent.

The Examiner stated that claim 23 of the instant application corresponds to claim 20 of the patent, and that claim 24 of the instant application corresponds to claim 20 of the patent, and that claim 24 of the instant application corresponds to claim 21 of the patent. The Examiner stated that, regarding claims 24-30 [sic 25-30] of the instant application, all of the elements of the claims are recited in claim 1 of the patent, that all of the aforementioned claims recite a tube segment that is carried by a balloon catheter having a shaft and an inflatable balloon, where the tube segment includes a radioactive material for administering a radiation dose which varies along a dimension of the tube segment, and that claim 1 of the patent limits the dimension to an axial or longitudinal dimension as the tube of that claim is only radioactive at a distal end thereof. The Examiner stated that since the more specific patented claims "anticipate" the broader claims of the instant application, the claims are not patentably distinct.

In response to the rejection of independent claims 1, 8 and 22 over Fischell et al., these claims have been amended to recite that the tube segment is longitudinally slid over the balloon. In Fischell, the radioactive source is attached to the balloon, either inside the balloon or outside the balloon. Fischell does not teach or suggest that a radioactive tube segment could be slid, longitudinally or otherwise, over the balloon.

In response to the rejection of independent claims 25 (over Columbo alone) and 28 (over Columbo combined with Hess'466) applicant has amended these claims to recite that the tube segment has varying concentrations of radioactive material for producing a radiation dose which varies along the tube segment. In the Columbo reference, the radioactive concentration is either present or not present, and when provided it has the same value.

In response to the obviousness-type double patenting rejection, applicant has compared claims 1-22 of applicant's prior U.S. Patent No. 6,200,256 B1 with the pending claims 1-4, 6-13 and 22-30 in this application, and finds significant differences between these claims sufficient to render the presently pending claims patentably distinct over the claims of the prior patent. In particular, present independent claims 1, 8 and 22 recite that the tube segment is slideable over the balloon, which feature is not in any of the patent claims. Pending independent claims 25 and 28 recite the varying radioactivity feature, which feature is not present in any of the patent claims. Applicant requests reconsideration and withdrawal of this rejection.

In view of the foregoing, applicants respectfully request withdrawal of the rejections of the pending claims and request allowance.

If a telephone interview would be of assistance in advancing prosecution of the subject application, the undersigned attorney invites the Examiner to telephone him at the telephone number provided below.

No fee is deemed necessary in connection with the filing of this Amendment, other than the fee for a one-month extension of time.

Application of : Judah Z. Weinberger
Serial No. : 09/803,773
Date Filed : March 12, 2001

If any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account Number 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Assistant Commissioner of Patents,
Washington, D.C. 20231.

10/10/02
Peter J. Phillips Date
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Application of : Judah Z. Weinberger
Serial No. : 09/803,773
Date Filed : March 12, 2001

Marked Up Copy of Amended Claims

1. (Twice Amended) A tube segment for treating a disease process in the vicinity of a luminal structure, said tube segment including radioactive material for producing radiation for treating a disease process, said tube segment being adapted to be longitudinally slid over and carried by a balloon catheter having a catheter shaft and balloon for insertion in the luminal structure, and being made of expandable and collapsible material, whereby the shape of the tube segment may be determined by the shape of the balloon.

8. (Twice Amended) An apparatus for treating a disease process in the vicinity of a luminal structure, comprising:

a balloon catheter having a shaft and an inflatable balloon; and

a tube segment adapted to be longitudinally slid over and carried by and cover said balloon, said tube segment including radioactive material, and being made of expandable and [callapsible] collapsible material, whereby the shape of the tube segment may be determined by the

Application of : Judah Z. Weinberger
Serial No. : 09/803,773
Date Filed : March 12, 2001

shape of the balloon.

22. (Twice Amended) A method for treating a disease process in the vicinity of a luminal structure comprising:

inserting a balloon catheter into a luminal structure, said balloon catheter having an inflatable balloon and a tube segment, slideable over the balloon catheter, of expandable and collapsible material and which includes radioactive material;

inflating the balloon with fluid to expand the tube segment and move the tube segment closer to the interior of the luminal structure to thereby administer a radiation dose to the luminal structure;

deflating the balloon and collapsing the tube segment; and

removing the balloon catheter including the tube segment after a desired radiation dose has been achieved.

25. (Twice Amended) A tube segment for treating a disease process in the vicinity of a luminal structure, said tube segment including radioactive material for producing radiation for treating a disease process, said

Application of : Judah Z. Weinberger
Serial No. : 09/803,773
Date Filed : March 12, 2001

tube segment having varying concentrations of radioactive material for producing a radiation dose which varies along at least one dimension of the tube segment.

28. (Twice Amended) An apparatus for treating a disease process in the vicinity of a luminal structure, comprising:

a balloon catheter having a shaft and an inflatable balloon; and

a tube segment adapted to be carried by and cover said balloon, said tube segment including radioactive material having varying concentrations of radioactive material for producing radiation for treating a disease process, said tube segment producing a radiation dose which varies along at least one dimension of the tube segment.